ARC 4454C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to USP general chapter 800

The Board of Pharmacy hereby amends Chapter 8, "Universal Practice Standards," and Chapter 20, "Compounding Practices," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code sections 147.76, 155A.2 and 155A.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 155A.2 and 155A.13.

Purpose and Summary

The United States Pharmacopeial Convention establishes national minimum standards for a number of health care-related topics. United States Pharmacopeia (USP) General Chapter 800, enforceable by the federal Food and Drug Administration, provides the national minimum standard for the proper handling of hazardous drugs to protect health care workers, patients, and the environment and will become effective (enforceable) December 1, 2019. This rule making establishes the Board's expectation that pharmacies handling hazardous drugs will be compliant with the standards identified in USP General Chapter 800. This rule making also provides an opportunity for pharmacies engaged in compounding to seek approval for delayed compliance to applicable USP General Chapters for no more than 18 months and authorizes the Board to establish a committee to grant or deny requests for delayed compliance.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 29, 2018, as **ARC 3978C**. An Amended Notice of Intended Action was published in the Iowa Administrative Bulletin on December 19, 2018, as **ARC 4172C**.

The Board received numerous comments from the public, health care associations, and the Administrative Rules Review Committee seeking either an 18-month delay of enforcement of USP General Chapter 800 or an opportunity for entities to seek approval from the Board for delayed compliance.

Since publication of the Notice, changes have been made in response to the comments received. These adopted rules provide an opportunity for pharmacies engaged in the compounding of hazardous drugs to seek approval for delayed compliance of applicable USP General Chapters and allow the Board to establish a committee to review such delayed compliance requests.

Adoption of Rule Making

This rule making was adopted by the Board on May 2, 2019.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs is anticipated or can be determined. It is unknown to what extent each individual pharmacy will need to implement protective measures to protect its personnel who handle hazardous drugs.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on June 26, 2019.

The following rule-making actions are adopted:

ITEM 1. Amend rule 657—8.5(155A) as follows:

657—8.5(155A) Environment and equipment requirements. There shall be adequate space, equipment, and supplies for the professional and administrative functions of the pharmacy pursuant to rule 657—8.3(155A). Space and equipment shall be available in an amount and type to provide secure, environmentally controlled storage of drugs ~~shall be available~~.

8.5(1) to **8.5(10)** No change.

8.5(11) *Hazardous drugs.* The pharmacy shall ensure pharmacy personnel and patients are adequately protected from unnecessary exposure to hazardous drugs. As of December 1, 2019, the pharmacy shall be in compliance with United States Pharmacopeia (USP) General Chapter 800 for handling hazardous drugs. A pharmacy engaged in compounding of hazardous drugs may request delayed compliance for specific requirements in USP General Chapter 800 pertaining to compounding, in accordance with rule 657—20.5(126,155A).

ITEM 2. Amend rule 657—20.5(126,155A) as follows:

657—20.5(126,155A) Delayed compliance. A pharmacy that cannot meet the requirements for full compliance with ~~these rules, including~~ applicable USP chapters~~, and that has not obtained from the board a waiver of the specific requirement or requirements~~ by the enforcement date established by USP shall not engage in compounding until the pharmacy is in full compliance with all requirements or the board has approved ~~a waiver of~~ delayed compliance for the specific requirement or requirements requested. The board may establish a committee to grant or deny requests for delayed compliance. The board or committee may grant a request for delayed compliance only if the pharmacy can demonstrate progress toward full compliance and adequate protection of the public health, safety, and welfare during the period of delayed compliance. The board or committee may only grant a request for delayed compliance of specific requirements in applicable USP chapters for a maximum of 18 months.

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